## Remarks

Claims 1-28 are pending in the Application. Claims 1-2, 4, 16-24, and 26-27 have been amended. No new matter has been added. Entry of the amendment is respectfully requested. Reconsideration is respectfully requested.

## The Applicable Legal Standards

Anticipation pursuant to 35 U.S.C. § 102 requires that a single prior art reference contain all the elements of the claimed invention arranged in the manner recited in the claim. *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983).

Anticipation under 35 U.S.C. § 102 requires in a single prior art disclosure, each and every element of the claimed invention arranged in a manner such that the reference would literally infringe the claims at issue if made later in time. *Lewmar Marine, Inc. v. Barient, Inc.*, 822 F.2d 744, 747, 3 USPQ2d 1766, 1768 (Fed. Cir. 1987).

Before a claim may be rejected on the basis of obviousness pursuant to 35 U.S.C. § 103, the Patent Office bears the burden of establishing that all the recited features of the claim are known in the prior art. This is known as *prima facie* obviousness. To establish *prima facie* obviousness, it must be shown that all the elements and relationships recited in the claim are known in the prior art. If the Office does not produce a *prima facie* case, then the Applicants are under no obligation to submit evidence of nonobviousness. MPEP § 2142.

Even if all of the features recited in the claim are known in the prior art, it is still not proper to reject a claim on the basis of obviousness unless there is a specific teaching, suggestion, or

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motivation in the prior art to produce the claimed combination. *Panduit Corp. v. Denison Mfg. Co.*, 810 F.2d 1561, 1568, 1 USPQ2d 1593 (Fed. Cir. 1987). *In re Newell*, 891 F.2d 899, 901, 902, 13 USPQ2d 1248, 1250 (Fed. Cir. 1989).

The teaching, suggestion, or motivation to combine the features in prior art references must be clearly and particularly identified in such prior art to support a rejection on the basis of obviousness. It is not sufficient to offer a broad range of sources and make conclusory statements. *In re Dembiczak*, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

It is respectfully submitted that the Action does not meet these burdens.

## The Claims Patentably Distinguish Over Gombrich

In the Action claims 1-8 and 11-18 were rejected under 35 U.S.C. § 102(b) as being anticipated by Gombrich et al. ("Gombrich"). Claims 9-10 and 19-27 were rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Gombrich. These rejections are respectfully traversed.

For brevity the Applicants do not necessarily present all of the reasons as to why the Gombrich reference does not anticipate nor render obvious the claims. The Applicants reserve the right to later present additional reasons. Nevertheless, Applicants' arguments herein show that the reference does not teach or suggest each and every feature, relationship, and step of the claimed invention arranged in the manner recited in the claims, as is required to sustain the rejections. Therefore, the Gombrich reference cannot anticipate nor render obvious the claims. Hence, Applicants' claims patentably distinguish over the applied reference. Therefore, it is

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respectfully submitted that the 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) rejections should be withdrawn.

**Claim 1**

Gombrich does not teach the recited features, relationships, and steps. For example, Gombrich does not teach generating a report, wherein the report includes machine readable indicia corresponding to at least one of the patients, and machine readable indicia corresponding to at least one item prescribed for the patient.

The Action (on page 3) alleges that in Gombrich the "printing on a sheet of bar code labels, patient specific bar code identifiers and the patient's name" (col. 12, lines 66-67, and col. 13, lines 1-2) is a form of report generation, and that "generating bar code labels for drugs in prescription with a printer" (col. 14, lines 7-11) is also a form of report generation. Applicants respectfully disagree.

The Applicants disagree with the Office's interpretation of the referenced sections of Gombrich. Nevertheless, even if it were somehow possible to interpret Gombrich's separate bar codes as separate reports, Gombrich would still not teach generating a report, where the report includes both machine readable indicia corresponding to at least one of the patients and machine readable indicia corresponding to at least one item prescribed for the patient.

Applicants respectfully submit that Gombrich does not disclose each and every step of the claimed invention arranged in the manner recited in the claim, as is required to sustain the rejection. The rejection of claim 1 is based on alleged teachings of Gombrich, not factual showings of what Gombrich actually teaches. Therefore, Gombrich cannot anticipate claim 1.

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## Claim 4

Gombrich does not teach the recited features, relationships, and steps. For example, Gombrich does not teach inputting data representative of giving the medical item to the patient to a <u>portable</u> terminal, <u>storing</u> data representative of the giving of the medical item in the portable terminal, and <u>transferring</u> data representative of the giving of the medical item from the portable terminal to the <u>computer</u>, where the computer is operative to include in the data store, data representative of the medical item having been given to the patient.

The Action (on page 4) alleges that Gombrich teaches the recited features at col. 11, lines 4-44. Applicants respectfully disagree. The relied upon section of Gombrich refers to a bar code reader (48). The bar code reader (48) is used to read bar codes (col. 8, lines 56-58). The bar code reader cannot constitute the recited portable terminal. The bar code reader is not a portable terminal capable of receiving inputted <u>data representative of the giving of a medical item to a patient</u>. Nor does the bar code reader store data representative of the giving of the medical item therein. Nor is the bar code reader capable of transferring data representative of the giving of the medical item from the bar code reader to a computer so that the computer is operative to include in a data store the data representative of the medical item having been given to the patient. Where does Gombrich teach that the bar code reader (48) stores information regarding the giving of a medical item to a patient, and then transfers this information to a computer/data store? Nor does Gombrich teach the other recited steps. Gombrich does not anticipate claim 4.

**Claim 16**

Gombrich does not teach the recited features, relationships, and steps. For example, Gombrich does not teach generating a report including machine readable indicia indicative of a medical item prescribed for a patient, where the report further includes information indicative of the patient.

The Action alleges that Gombrich has a bar code label on a drug package which is interpreted as a report. Applicants respectfully disagree. Even if Gombrich had a bar code label on a drug package, there is no evidence that the drug package further includes information indicative of the patient. Gombrich does not teach a report including both machine readable indicia indicative of a medical item prescribed for a patient and further information indicative of the patient. Gombrich drug packages do not contain patient information. Gombrich's drug packages are generic and are not assigned to any particular patient. Thus, a bar code label on a drug package still would not constitute the recited report. It follows that Gombrich cannot anticipate claim 16.

**Claim 19**

Gombrich does not teach or suggest the recited features, relationships, and steps. For example, Gombrich does not teach or suggest dispensing a medical item from a medical item dispenser responsive to reading machine readable indicia on a report in inputting to a computer, data corresponding to at least one medical item prescribed for the one patient. Where does Gombrich teach or suggest dispensing a medical item from a medical item dispenser responsive to reading machine readable indicia on a report? The Action (on page 8) admits that Gombrich

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does not even teach or suggest "the dispensing of one medical item from a medical item dispenser." Nor does Gombrich teach or suggest a medical item dispenser. It follows that Gombrich cannot teach or suggest dispensing a medical item from a medical item dispenser responsive to reading machine readable indicia, especially where the machine readable indicia is on a report, and further especially where the machine readable indicia is read during inputting data corresponding to at least one medical item prescribed for the one patient to a computer. Nor does Gombrich teach or suggest the other recited steps.

The only suggestion for having a medical item dispenser (including dispensing a medical item from a medical item dispenser responsive to reading machine readable indicia) is found in Applicants' own novel disclosure. It follows that the alleged modification of Gombrich (and the rejection) is based on hindsight reconstruction of the recited invention based on Applicants' disclosure, which is impermissible. Therefore, it would not have been obvious to one having ordinary skill in the art to have modified Gombrich to have produced the claimed invention. Nor does Gombrich teach or suggest the recited features and relationships. The Office does not factually support any *prima facie* conclusion of obviousness. Thus, it is respectfully submitted that the 35 U.S.C. § 103(a) rejection should be withdrawn.

**Claim 20**

Gombrich does not teach or suggest the recited features, relationships, and steps. For example, Gombrich does not teach or suggest <u>storing</u> in a data store, data representative that a medical item has been taken for use by the one patient, <u>responsive to</u> the medical item being <u>dispensed</u> from a medical item dispenser. Gombrich does not associate the dispensing of a

medical item from a dispenser with the medical item having been taken for use by a patient. Nor does Gombrich store this information in a data store responsive to the dispensing. Where does Gombrich teach or suggest dispensing a medical item from a medical item dispenser? The Action (on page 8) admits that Gombrich does not even teach or suggest "the dispensing of one medical item from a medical item dispenser." Nor does Gombrich teach or suggest a medical item dispenser. It follows that Gombrich cannot teach or suggest storing in a data store, data representative that a medical item has been taken for use by the one patient, responsive to the medical item being dispensed from a medical item dispenser. Nor does Gombrich teach or suggest the other recited steps.

The only suggestion for having a medical item dispenser (including storing in a data store, data representative that a medical item has been taken for use by the one patient, responsive to the medical item being dispensed from a medical item dispenser) is found in Applicants' own novel disclosure. It follows that the alleged modification of Gombrich (and the rejection) is based on hindsight reconstruction of the recited invention based on Applicants' disclosure, which is impermissible. Therefore, it would not have been obvious to one having ordinary skill in the art to have modified Gombrich to have produced the claimed invention. Nor does Gombrich teach or suggest the recited features and relationships. Thus, the Office has not presented a *prima facie* showing of obviousness.

**Claim 26**

Gombrich does not teach or suggest the recited features, relationships, and steps. For example, Gombrich does not teach or suggest storing data in a bedside terminal positioned in

generally <u>fixed</u> relation adjacent a bedside area of a patient, indicative that the one medical item has been used in the medical treatment of the one patient.

The Action alleges that Gombrich's terminals (45) are placed at a bedside area of a patient. Applicants respectfully disagree. The Action relies on Gombrich at col. 8, lines 26-30. However, Gombrich does not teach or suggest bedside positioning of terminals. Nor does Gombrich teach or suggest having a bedside terminal positioned in generally <u>fixed</u> relation adjacent a bedside area of a patient. The relied on section of Gombrich indicates that terminals (45) may be located in non public (e.g., non patient) secured areas, such as the pharmacy, laboratory, supply room, in X-ray, in radiology, billing department, or at a nurses' station. There is no teaching or suggestion of a bedside terminal positioned in generally fixed relation adjacent a bedside area of a patient, or of storing data in the bedside terminal indicative that a medical item has been used in the medical treatment of that bedside area patient. Contrarily, Gombrich teaches away from having a fixed bedside terminal. For example, Gombrich's Figure 1 explicitly teaches keeping the terminals (45) outside of patients' rooms.

Again, the alleged modification of Gombrich (and the rejection) is based on hindsight reconstruction of the recited invention based on Applicants' disclosure, which is impermissible. Therefore, it would not have been obvious to one having ordinary skill in the art to have modified Gombrich to have produced the claimed invention. The Office does not factually support any *prima facie* conclusion of obviousness. Thus, it is respectfully submitted that the 35 U.S.C. § 103(a) rejection should be withdrawn.

## The Dependent Claims

Each of the dependent claims depends directly or indirectly from an independent claim. The independent claims have been shown to be allowable. Thus, it is asserted that the dependent claims are allowable on the same basis.

Furthermore, each of the dependent claims additionally recites specific features, relationships, and steps that patentably distinguish the claimed invention over the applied art. Gombrich does not teach or suggest the features, relationships, and steps that are specifically recited in these dependent claims. Thus, it is respectfully submitted that these dependent claims are further allowable due to the recitation of such additional features, relationships, and steps.

For example, with regard to claim 2, Gombrich does not teach reading machine readable indicia corresponding to a medical item with a reading device, especially where the machine readable indicia corresponding to the medical item is included in a report with machine readable indicia corresponding to at least one of the patients. Gombrich does not anticipate claim 2.

With regard to claim 9, Gombrich does not teach or suggest a bed label attached to a bed of a patient, and reading machine readable indicia on the bed label with a reading device. The Office has not presented a *prima facie* showing of obviousness.

With regard to claim 12, Gombrich does not teach a report including <u>both</u> machine readable indicia corresponding to at least one of the patients <u>and</u> machine readable indicia corresponding to at least one medical item prescribed for the patient. Gombrich does not anticipate claim 12.

With regard to claim 14, Gombrich does not teach generating a report including information indicating that a medical item has been taken for use by, but not yet given, to the patient. Gombrich does not anticipate claim 14.

With regard to claim 15, Gombrich does not teach that the report generated in claim 14 includes information indicative that an authorized user has taken the medical item for use by the patient. Gombrich does not anticipate claim 15.

With regard to claim 21, Gombrich does not teach or suggest that a data store includes data representative that a medical item has been taken by an authorized user. The Office has not presented a *prima facie* showing of obviousness.

With regard to claim 25, Gombrich does not teach or suggest storing data in a bedside terminal adjacent a patient, where the data is indicative that a medical item has been used in the medical treatment of the patient. Again, the Office has not presented a *prima facie* showing of obviousness.

### Fees For Additional Claims

Please charge the fees associated with the submission of three (3) additional independent claims and one (1) claim in excess of twenty claims and any other fee due to deposit account 10-0637.

## Versions With Markings To Show Changes Made

**In the Claims**

1. (once amended) A method comprising the steps of:

    (a)      storing in a data store in operative connection with a computer, data representative of a plurality of patients for whom medical items may be used;

    (b)      generating a report, wherein the report includes machine readable indicia corresponding to at least one of the patients <u>and machine readable indicia corresponding to at least one item prescribed for the patient</u>;

    (c)      reading the machine readable indicia on the report corresponding to a patient with a reading device;

    (d)      inputting to the computer, data representative of a medical item, wherein the computer is operative to include in the data store, data representative of the taking of the medical item for use by the patient;

(e)     inputting data to the computer representative of giving the medical item to

the patient, wherein the computer is operative to include in the data store,

data representative of the medical item having been given to the patient.


2. (once amended) The method according to claim 1 wherein step (a) further comprises storing in

the data store, data representative of medical items prescribed for each patient, [and wherein step

(b) further comprises including on the report, machine readable indicia corresponding to at least

one of the medical items prescribed for the patient,] and wherein step (d) comprises reading the

machine readable indicia corresponding to the medical item with the reading device.


4. (once amended) [The] A method [according to claim 3 wherein step (e) comprises]

comprising:


(a)     storing in a data store in operative connection with a computer, data

representative of a plurality of patients for whom medical items may be

used;


(b)     generating a report, wherein the report includes machine readable indicia

corresponding to at least one of the patients;

(c)    reading the machine readable indicia on the report corresponding to a patient with a reading device;

(d)    inputting to the computer, data representative of a medical item, wherein the computer is operative to include in the data store, data representative of the taking of the medical item for use by the patient;

(e)    inputting [the] data representative of giving the medical item to the patient to a portable terminal, storing data representative of the giving of the medical item to the patient in the portable terminal, and transferring data representative of the giving of the medical item to the patient from the portable terminal to the computer, wherein the computer is operative to include in the data store, data representative of the medical item having been given to the patient.

16. (once amended) A method comprising the steps of:

(a)    storing in a data store in operative connection with a computer, data representative of a plurality of patients for whom medical items may be used;

(b)      storing in the data store, data representative of a plurality of medical items

prescribed for use by corresponding patients;

(c)      generating a report including machine readable indicia indicative of a

medical item prescribed for a patient, wherein the report further includes

information indicative of the patient;

[(c)]     (d)      inputting to the computer, data corresponding to one of the plurality of

patients;

[(d)]     (e)      inputting to the computer, data corresponding to at least one medical item

indicated by data in the data store as prescribed for the one patient,

including reading with a reading device the machine readable indicia on

the report;

[(e)]     (f)      storing in the data store, data representative that the at least one medical

item has been taken for use by the one patient;

[(f)]     (g)      using the at least one medical item in the medical treatment of the one

patient; and

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[(g)] (h) inputting data to the computer indicative that the at least one medical item

has been used in the medical treatment of the one patient, wherein the

computer is operative to include in the data store, data representative that

the at least one medical item has been used in the medical treatment of the

one patient.


17. (once amended) The method according to claim 16 and prior to step (d) [(c) further]

comprising including on the report, [the step of generating a report including] machine readable

indicia indicative of the one patient [and the one medical item prescribed for the patient], and

wherein step (d) [(c)] comprises reading with a reading device the machine readable indicia

indicative of the one patient on the report.


18. (once amended) The method according to claim 16 [17] wherein step (h) [(d)] comprises

[reading with a reading device the machine readable indicia on the report] inputting the data

representative that the at least one medical item has been used in the medical treatment of the one

patient to a portable terminal, storing data representative that one medical item has been used in

the medical treatment of the at least one patient in the portable terminal, and transferring data

representative that the at least one medical item has been used in the medical treatment of the one

patient from the portable terminal to the computer.


19. (once amended) [The] A method [according to claim 18 and further] comprising:

(a)     storing in a data store in operative connection with a computer, data representative of a plurality of patients for whom medical items may be used;

(b)     storing in the data store, data representative of a plurality of medical items prescribed for use by corresponding patients;

(c)     inputting to the computer, data corresponding to one of the plurality of patients;

(d)     inputting to the computer, data corresponding to at least one medical item prescribed for the one patient;

(e)     dispensing the at least one medical item from a medical item dispenser responsive to reading [the] machine readable indicia on [the] a report in step (d).

20. (once amended) [The] A method [according to claim 19 wherein step (e) is executed] comprising:

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(a) storing in a data store in operative connection with a computer, data representative of a plurality of patients for whom medical items may be used;

(b) storing in the data store, data representative of a plurality of medical items prescribed for use by corresponding patients;

(c) inputting to the computer, data corresponding to one of the plurality of patients;

(d) inputting to the computer, data corresponding to at least one medical item prescribed for the one patient;

(e) storing in the data store, data representative that the at least one medical item has been taken for use by the one patient, responsive to the at least one medical item being dispensed from [the] a medical item dispenser;

(f) using the at least one medical item in the medical treatment of the one patient; and

(g)   inputting data to the computer indicative that the at least one medical item has been used in the medical treatment of the one patient, wherein the computer is operative to include in the data store, data representative that the at least one medical item has been used in the medical treatment of the one patient.

21. (once amended) The method according to claim 19 and prior to the dispensing step, further comprising the steps of:

storing in the data store, data representative of a plurality of authorized users;

inputting to the computer, user data;

comparing the input user data to the data stored concerning authorized users and determining that the input user data corresponds to one authorized user;

wherein the step of dispensing the at least one medical item is carried out responsive to the determination that the input user data corresponds to one authorized user, and further comprising storing in [wherein in step (e)] the data store [includes] data representative that the at least one medical item has been taken by the one authorized user.

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22. (once amended) The method according to claim 16 wherein step (e) [(d)] comprises storing data in a portable terminal adjacent a bedside of the patient indicative that the at least one medical item has been used in the medical treatment of the one patient, and thereafter placing the portable terminal in operative connection with the computer, wherein information indicative of the use of the at least one medical item in the treatment of the patient is passed from the portable terminal to the computer.

23. (once amended) The method according to claim 22 wherein step (h) [(g)] further comprises reading machine readable indicia on a patient associated item in proximity to the patient with a terminal reading device in operative connection with the portable terminal, wherein the data indicative that the at least one medical item has been given to the patient is stored in the portable terminal responsive to reading the machine readable indicia on the patient associated item.

24. (once amended) The method according to claim 23 wherein in step (h) [(g)] the patient associated item from which the machine readable indicia is read comprises at least one of a band worn by the patient, a bed label or a chart.

26. (once amended) [The] A method [according to claim 22 and further] comprising [the step of]:

(a) storing in a data store in operative connection with a computer, data representative of a plurality of patients for whom medical items may be used;

(b) storing in the data store, data representative of a plurality of medical items prescribed for use by corresponding patients;

(c) inputting to the computer, data corresponding to one of the plurality of patients;

(d) inputting to the computer, data corresponding to at least one medical item prescribed for the one patient;

(e) storing in the data store, data representative that the at least one medical item has been taken for use by the one patient;

(f) using the at least one medical item in the medical treatment of the one patient; and

(g)     storing data in a bedside terminal positioned in generally fixed relation adjacent a bedside area of the one patient, indicative that the at least one medical item has been used in the medical treatment of the one patient.
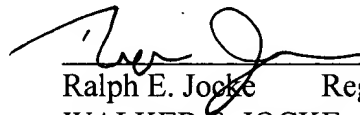
27. (once amended) The method according to claim 26 and further comprising storing data in a portable terminal adjacent a bedside of the patient indicative that the at least one medical item has been used in the medical treatment of the one patient, wherein step (g) [(h)] includes passing the data between the portable terminal and the bedside terminal.

## Conclusion

Each of Applicants' pending claims specifically recite steps, features, and relationships that are neither disclosed nor suggested in any of the applied prior art. Furthermore, the applied prior art is devoid of any such teaching, suggestion, or motivation for combining features of the applied art so as to produce Applicants' invention. Allowance of all of Applicants' pending claims is therefore respectfully requested.

The undersigned will be happy to discuss any aspect of the Application by telephone at the Examiner's convenience.

Respectfully submitted,

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